PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Miao and Kay	EXAMINER: Burkhart
APPLICATION NO.: 09/884,901	ART UNIT: 1633
FILED: June 18, 2001	CONF. NO: 1704
FOR: **LIVER-SPECIFIC GENE EXPRESSION CASSETTES, AND METHODS OF USE**	

Declaration of Carol H. Miao and Mark A. Kay

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

We, Carol H. Miao and Mark A. Kay, declare and affirm as follows:

1. We are co-inventors of the subject matter described and claimed in U.S. Patent Application No. 09/884,901, filed June 18, 2001 entitled LIVER-SPECIFIC GENE EXPRESSION CASSETTES, AND METHODS OF USE.

2. The subject matter as presently claimed relates to an expression cassette for expressing human Factor IX. The expression cassette is comprised of a hepatic locus control element, a hepatic promoter, a Factor IX coding sequence, a Factor IX Intron A, and a polyadenylation signal. In some embodiments, the cassette additionally comprises a 3' untranslated region.

3. An expression cassette previously invented by Dr. Kay is described in U.S. Patent No. 6,936,243, issued to Snyder *et al.* This previously described cassette included a promoter, a Factor IX coding sequence, and a polyadenylation signal.

4. Features of the presently claimed expression cassette that are not earlier invented by Dr. Kay are joint contributions by both of us.

5. For example, the hepatic locus control element in the claimed expression cassette was a joint contribution by both of us.

6. By way of another example, inclusion of the Factor IX Intron A, and the optional 3' untranslated region, in the claimed expression cassette were contributed by both of us.

7. By way of another example, the discovery that the claimed expression cassette absent a viral vector achieves long term expression of Factor IX *in vivo* was an inventive contribution of both of us. This discovery is currently set forth, for example, in claims 2-3, 36-38, and 40-42.

We declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the Unites States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully submitted,

5/24/2007
Date

Carol H. Miao

Date

Mark A. Kay

4. Features of the presently claimed expression cassette that are not earlier invented by Dr. Kay are joint contributions by both of us.

5. For example, the hepatic locus control element in the claimed expression cassette was a joint contribution by both of us.

6. By way of another example, inclusion of the Factor IX Intron A, and the optional 3' untranslated region, in the claimed expression cassette were contributed by both of us.

7. By way of another example, the discovery that the claimed expression cassette absent a viral vector achieves long term expression of Factor IX *in vivo* was an inventive contribution of both of us. This discovery is currently set forth, for example, in claims 2-3, 36-38, and 40-42.

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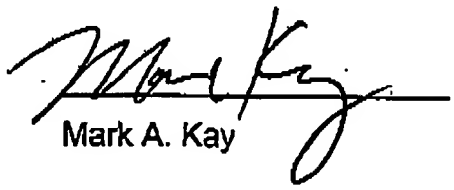
Respectfully submitted,

_____ _____

Date Carol H. Miao

5/24/07 

Date Mark A. Kay

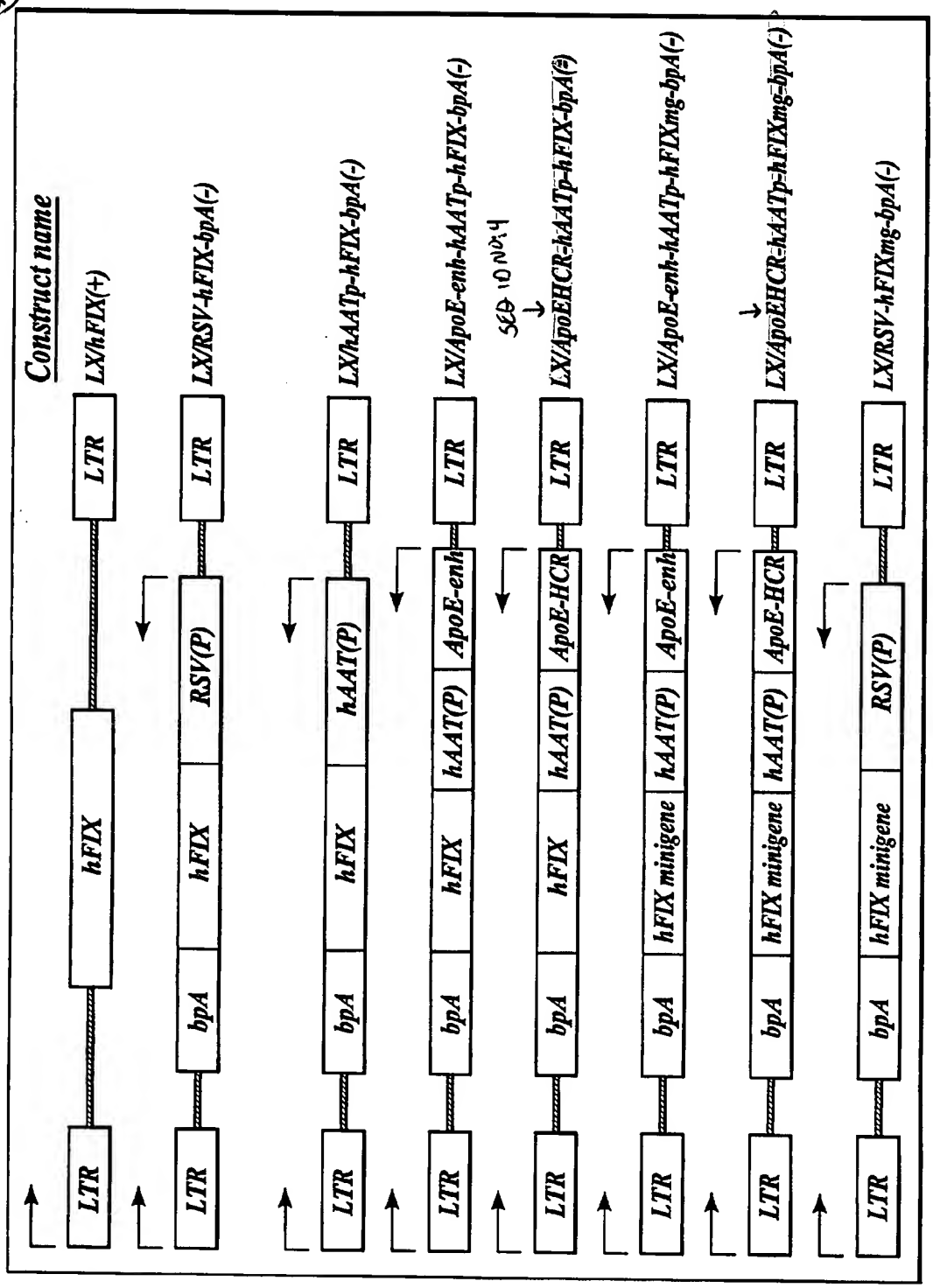


Fig. 2A.

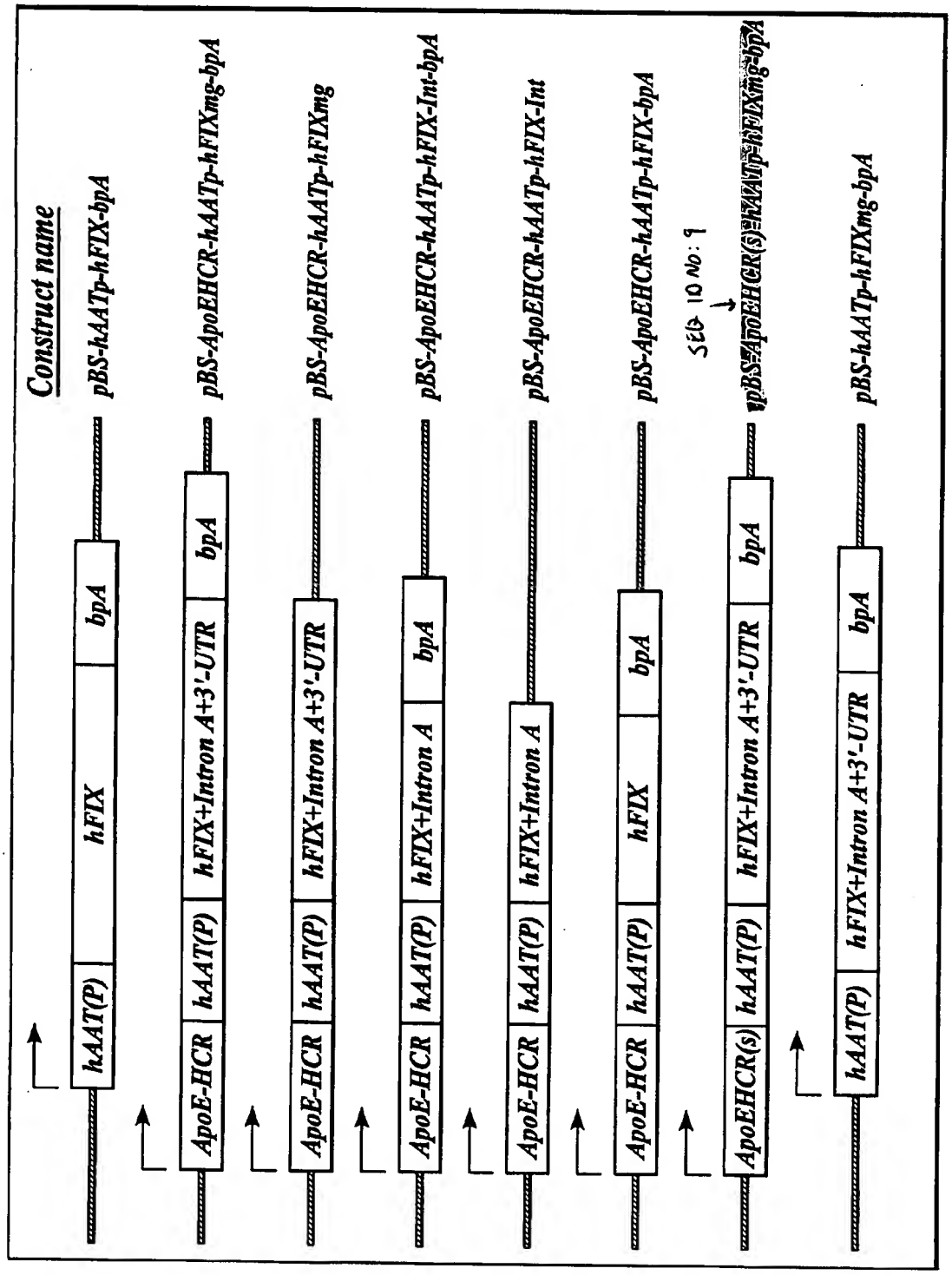

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Fig. 2B.

-continued

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Ala Asp Lys Glu Tyr Thr Asn Ile Phe Leu Lys Phe Gly Ser Gly Tyr
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Val Ser Gly Trp Gly Arg Val Phe His Lys Gly Arg Ser Ala Leu Val
        355                 360                 365

Leu Gln Tyr Leu Arg Val Pro Leu Val Asp Arg Ala Thr Cys Leu Arg
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Ser Thr Lys Phe Thr Ile Tyr Asn Asn Met Phe Cys Ala Gly Phe His
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Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte ALEXANDER R. POKORA
and MARK A. JOHNSON

Appeal No. 95-2444
Application 07/973,655[1]

ON BRIEF

Before RONALD H. SMITH, Administrative Patent Judge and McKELVEY, Senior Administrative Patent Judge and HANLON, Administrative Patent Judge.

HANLON, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 1-12, all of the claims pending in the application.

The claims are directed to a process for treating a

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[1] Application for patent filed November 9, 1992.

lignocellulosic pulp with soybean peroxidase in the presence of a peroxide and removing lignin from the pulp. Appellants disclose that suitable pulps for the practice of the invention include kraft pulp (Specification, p.4). Claim 1 is illustrative of the subject matter on appeal and reads as follows:

1. A process which comprises treating a lignocellulosic pulp with soybean peroxidase in the presence of a peroxide, and removing lignin from said pulp.

The references relied upon by the examiner are:

Johnson et al. (Johnson)	5,147,793	Sep. 15, 1992
Vaherl et al. (Vaherl) (European Patent Application)	0 395 792	Nov. 7, 1990
Canadian Patent Application	2,019,411	Dec. 22, 1990

The following rejections are at issue in this appeal:

(1) Claim 1 is rejected under 35 U.S.C. § 102(a) or (e) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over the '793 patent.[2]

(2) Claims 1-4, 6 and 9-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Canadian patent application no.

[2] The examiner refers to U.S. Patent No. 5,147,793, as "Cyrus, Jr. et al." throughout the final Office action and the answer, and appellants refer to this same reference as "Johnson '793." We will refer to U.S. Patent No. 5,147,793 as "the '793 patent".

2,019,411 in view of the '793 patent.

(3) Claims 7 and 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Canadian patent application no. 2,019,411 in view of the '793 patent, and further in view of the admitted prior art (Specification, p.5, lines 20-22).

(4) Claim 5 is rejected under 35 U.S.C. § 103 as being unpatentable over Canadian patent application no. 2,019,411 in view of the '793 patent, and further in view of European patent application no. 395,792.

Grouping of claims

According to appellants, "[f]or purposes of this appeal, all claims stand or fall together" (Brief, p.3). Therefore, dependent claims 2-12 stand or fall with the patentability of independent claim 1.

Rejection of claim 1 under 35 U.S.C. § 102(a) or (e) or, in the alternative, under 35 U.S.C. § 103 over the '793 patent

The '793 patent discloses that soybean peroxidase is useful "in enzymatic bleaching of Kraft pulp" (col. 10, lines 44-45). The examiner maintains that this teaching either anticipates or renders claim 1 obvious (Answer, pp.2-3).

Appellants argue that (Brief, pp.3-4):

> Johnson '793 is not a proper reference to serve as a basis of rejection for the claims under 35 U.S.C. §102(a) or (e). The inventors, Mr. Pokora and Mr. Johnson, along with Mr. Cyrus, Jr. have submitted a Declaration under 37 C.F.R. §1.132 which states that they are the joint inventors of Johnson '793 and that Mr. Johnson and Mr. Pokora are the inventors of the process for using soybean peroxidase to bleach Kraft pulp described in the Johnson '793 patent. These Declarations eliminate Johnson '793 as prior art because they establish that the reference to bleaching Kraft pulp in Johnson '793 is not the disclosure or invention of another, but rather is the invention of Johnson and Pokora, the applicants.

The declaration under 37 CFR § 1.132 reads, in pertinent part, as follows:

> We, Mark A. Johnson, Alexander R. Pokora and William L. Cyrus, Jr., declare and state the following:
>
> (1) We are joint inventors of U.S. Patent No. 5,147,793;
>
> (2) The subject matter relating to the use of soybean peroxidase in enzymatic bleaching of kraft pulp at column 10, lines 44-45 of U.S. Patent No. 5,147,793, but not claimed therein, is the invention of Mark A. Johnson and Alexander R. Pokora and is not the invention of William L. Cyrus, Jr.; and
>
> (3) Mark A. Johnson and Alexander R. Pokora conceived of the subject matter

> disclosed and claimed in U.S. Patent Application No. 07/973,655 prior to the filing date of U.S. Patent No. 5,147,793.

The declaration was signed by the three patentees of the '793 patent, Mark A. Johnson, Alexander R. Pokora and William L. Cyrus, Jr.[3]

The examiner maintains that the declaration fails to remove the '793 patent as prior art under 35 U.S.C. § 102(a) and (e) for the reason that (Answer, p.5):

> [T]he claims of CYRUS, JR. ET AL call for the ""biocatalytic oxidation of an oxidizable substrate". The claims are not limited to the polymerization reactions of the Examples. When CYRUS JR. ET AL is read in view of its specification the claimed "biocatalytic oxidation" would include the disclosed "bleaching", and the claimed "oxidizable substrate" would include the disclosed "kraft pulp". Thus the claims of CYRUS JR. ET AL would include bleaching of Kraft pulp which includes the delignification (Kraft bleaching and/or delignifying) of lignocellulosic material (pulp), see the instant specification, page 3, lines 18-22. Thus the claimed subject matter of the instant Application, was disclosed *and* claimed in Patent No. 5,147,793.

We note at the outset that the declarants expressly state

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[3] Three copies of this declaration were received, one signed by Mark A. Johnson dated December 9, 1993, one signed by William L. Cyrus, Jr. dated December 13, 1993, and one signed by Alexander R. Pokora dated December 28, 1993.

that "[t]he subject matter relating to the use of soybean peroxidase in enzymatic bleaching of kraft pulp at column 10, lines 44-45 of U.S. Patent No. 5,147,793" is not claimed therein (Declaration, ¶2). Claim 1 of the '793 patent recites a method for biocatalytic oxidation of an oxidizable substrate comprising (1) preparing a solution of the oxidizable substrate and (2) contacting the solution with soybean hulls in the presence of a peroxide. First, the treated lignocellulosic pulp in appellants' claim 1 is not in solution. Second, soybean hulls are not the same as soybean peroxidase, required in appellants' claim 1. Rather, soybean hulls are one of several elements used to produce soybean peroxidase ('793 patent, col. 12, line 46 through col. 13, line 3; appellants' specification, p.3, lines 22-24). Therefore, the same invention is not claimed in appellants' application and the '793 patent.

The declaration under 37 CFR § 1.132 is sufficient and removes the '793 patent as available prior art under 35 U.S.C. § 102(a) and (e). See MPEP § 716.10 (6th ed. Rev. 2, July 1996) ("When subject matter, disclosed but not claimed in a patent application issued jointly to S and another, is claimed in a later application filed by S, the joint patent is a valid reference available as prior art under 35 U.S.C. 102(a), (e), or

(f) unless overcome by . . . an unequivocal declaration by S under 37 CFR 1.132 that he or she conceived or invented the subject matter disclosed in the patent."); see also In re DeBaun, 687 F.2d 459, 463, 214 USPQ 933, 936 (CCPA 1982); In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). Accordingly, we reverse the rejections based on the '793 patent alone and the rejections based on the '793 patent in combination with any other reference or references.

The decision of the examiner is reversed.

REVERSED

RONALD H. SMITH Administrative Patent Judge	)
FRED E. McKELVEY, Senior Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND
ADRIENE LEPIANE HANLON Administrative Patent Judge	) INTERFERENCES

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Dayton, Ohio 45401-8801